DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 22, 2014

Micro Therapeutics, Inc. d/b/a Ev3 Neurovascular
Mr. Larry Boucher
Sr. Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

Re: K141491
Trade/Device Name: Solitaire 2 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Thrombus Retriever
Regulatory Class: Class II
Product Code: NRY
Dated: August 20, 2014
Received: August 21, 2014

Dear Mr. Larry Boucher,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141491

Device Name
Solitaire 2 Revascularization Device

Indications for Use *(Describe)*
The Solitaire™ 2 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IVt-PA) or fail IVt-PA therapy are candidates for treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Owner: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Contact Person: Larry Boucher
Senior Regulatory Affairs Specialist
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Date Summary Prepared: 20 August 2014

Trade Name of Device: Solaitaire™ 2 Revascularization Device, 4x40mm

Common Name of Device: Catheter, Thrombus Retriever

Classification of Device: 21 CFR 870.1250 – Class II

Predicate Device: Solitaire™ 2 Revascularization Device, 510(k)#: K123378

Solitaire™ FR Revascularization Device (Biocompatibility)
510(k)#: K113455

Performance Data: The following bench testing was performed in support of the Solitaire™ 2 4x40 device and to establish substantial equivalence to the Solitaire™ 2 Revascularization Device:

- Dimensional Testing
- Delivery Force Testing
- Retrieval Force Testing
- Durability Testing
- Performance (Clot Retrieval) Testing
- Radial Force (in-process)

The following test data was adopted from the predicate device:

- A_f Temperature Testing
- Kink Resistance Testing
- System Tensile Testing

- Distal Marker Testing
- Torque Response Testing
- Radiopacity Testing

Biocompatibility, sterilization, and aging data were also adopted from the predicate device as there is no change to the materials of construction, design, manufacturing process, or packaging for the addition of this additional model.

Animal studies were performed to assess the safety and usability of the Solitaire™ 2 4x40 device compared to the previously cleared Solitaire™ 2 4x20 device. No clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology of the device.

Conclusion: The Solitaire™ 2 4x40 device is substantially equivalent to the currently cleared Solitaire™ 2 device based on the successful completion of non-clinical bench and animal testing as well as similar principles of design, operation and indications for use.

Device Description:

The Solitaire™ 2 device is designed to restore blood flow in subjects experiencing ischemic stroke due to large intracranial vessel occlusion within 8 hours of symptom onset. It is indicated for subjects who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy. The distal nitinol portion of the device facilitates clot retrieval and has Pt-Ir radiopaque markers on the proximal and distal ends.

This purpose of this application is to add one (1) new model number (SFR2-4-40) to the Solitaire™ 2 Revascularization Device family. The additional model will be identical to the currently cleared Solitaire™ 2 4x20 (SFR2-4-20) model, with the exception of a longer retriever length.

Indications for Use:

The Solitaire™ 2 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Device Comparison

The table below provides a comparison of the technological characteristics of the Solitaire™ 2 4x40 model and the currently cleared Solitaire™ 2 Revascularization Device.

	Solitaire™ 2 (K123378)	Solitaire™ FR (K113455)	Solitaire™ 2 4x40	Rationale for Difference (if applicable)
Indication for Use	The Solitaire™ 2 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	Same	Same	N/A
Method of Supply	Stored within dispenser coil, Tyvek pouch, & shipping carton	Same	Same	N/A
Sterilization Method	Ethylene Oxide	Same	Same	N/A
Device Sizes	4x15mm 4x20mm 6x20mm 6x30mm	Same	4x40mm	The difference in size is due to the extra working length of the device. Bench and animal testing have demonstrated that the extra working length does not affect the safety and effectiveness of the device.
Materials				
Stent	Nitinol	Same	Same	N/A
Push-wire	Nitinol	Same	Same	N/A
Markers	90% Platinum/ 10% Iridium	Same	Same	N/A
Push-wire Shrink Tubing	PTFE	Same	Same	N/A
Introducer Sheath	PTFE/Grilamid	Same	Same	N/A

Sterilization and Shelf Life

The currently cleared Solitaire™ 2 Revascularization Device was adopted into the EO sterilization cycle originally cleared under K1113455 for the Solitaire™ FR Revascularization Device. The materials of construction, design, manufacturing process, and packaging are identical to the predicate device. Therefore no additional validation testing is required.

Residual testing for the Solitaire™ 2 4x40mm device was adopted from the Solitaire™ 2 Revascularization Device as the materials of constructions and the manufacturing process are identical to the currently cleared Solitaire™ 2 device. In addition, the surface area of the Solitaire™ 2 4x40mm device is 5.2% less than the currently cleared Solitaire™ 2 6x30mm device.

Aging studies for the Solitaire™ 2 Revascularization Device have established the product and packaging remain functional and maintain sterility for 2 years. Aging studies for packaging integrity (per ASTM F2096-11), seal strength and device functionality were performed and met all acceptance criteria. The materials of construction, design, manufacturing process, and packaging of the Solitaire™ 2 4x40mm device are identical to the predicate device. Therefore the existing aging and packaging data has been adopted for the new model number.

Biocompatibility

Biocompatibility data for the Solitaire device family was tested for the for the Solitaire™ FR Revascularization device. The biocompatibility data for the Solitaire™ FR device has been adopted for the Solitaire™ 2 4x40mm device as no new materials have been introduced into the manufacturing process or the finished device.

Performance Data – Bench

A summary of the non-clinical bench testing performed for the Solitaire™ 2 4x40mm model is presented in the table below.

Test	Method	Conclusion
Total System Length	Samples were measured from the proximal tip of the push-wire to the distal-most tip of the finger marker coils.	All devices met acceptance criteria.
Distal Tip to Fluoro Safe Marker Length	Samples were measured from the distal tip of the device to the distal side of the proximal fluoro safe marker.	All devices met acceptance criteria.

Test	Method	Conclusion
Delivery Force	Peak delivery force was measured through a representative tortuous anatomical model.	All devices met acceptance criteria. Delivery force same as the predicate device.
Retrieval Force	Retrieval force was measured through a representative tortuous anatomical model.	All devices met acceptance criteria. Retrieval force same as the predicate device.
Radial Force	The radial force was measured 100% in-process.	Radial force was measured 100% in-process on DVT builds.
Durability	Samples were evaluated on their ability to withstand delivery and withdrawal forces in a representative tortuous model beyond the recommended number of passes and re-sheathings allowed per the IFU	All devices showed no irregularities, breaks, kinks, marker coil migration, glue separations, or other observed defects after all attempts. Durability same as the predicate device.
Performance	Test samples were evaluated for their ability to restore blood flow and retrieve soft clot from a 4mm vessel and hard clot in a 2mm vessel in a representative tortuous model.	All devices successfully retrieved the soft and firm clots from the respective vessels. Performance is the same as the predicate device.

Performance Data – Animal

An acute and 30 day animal study was performed that assessed safety and usability of the Solitaire™ 2 4x40 device as compared to the Solitaire 2 4x20 predicate device. A total of twelve swine were evaluated with a total of 3 passes and 6 resheathings across selected sections of vessels, with six (6) swine used for the acute study and six (6) swine used for the chronic 30 day study. A total of 4 vessels per animal were treated with two (2) vessels receiving the control device and two (2) vessels treated with the test device. Safety was evaluated for tissue damage, hemorrhage, and thrombi using angiographic images and histopathological evaluation.

Histological findings of the Solitaire™ 2 4x40 and the predicate device for the acute and chronic study demonstrated that the vessel response to neurothrombectomy was comparable between the two devices with no histological remarkable difference in the vessel in regards to tissue injury, hemorrhagic evaluation and thrombogenic evaluation.

Usability for the acute and chronic study were assessed by an interventionalist on the following attributes after each pass: delivery through catheter, ability to position stent retriever at intended target zone, ability to deploy retriever, ability to re-sheath and reposition, ability to retrieve the device through a guide catheter and device condition. The safety and usability results from the acute and 30-day animal studies suggest that the Solitaire™ 2 4x40 device is safe, usable and is equivalent to the predicate device.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the new model number. Substantial equivalence of the Solitaire™ 2 4x40 device has been established to the predicate device through the results of bench and animal testing.